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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,808	07/22/2003	Raymond G. Goodwin	03260-0148-04000	5275

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EXAMINER

BRANNOCK, MICHAEL T

ART UNIT	PAPER NUMBER
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1649

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/623,808

Applicant(s)

GOODWIN ET AL.

Examiner

Michael Brannock

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>072203</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application: Claims and Amendments

Applicant is notified that the amendments put forth on 11/15/2006, have been entered in full. It is noted that these amendments were presented on May 26, 2004 but were apparently not matched to the application. Additionally, the restriction requirement mailed June 15, 2006 was directed to original claims 1-47, which had been canceled in the May 26, 2004 amendment, thus the restriction requirement is withdrawn. Claims 48-76 are currently pending and under examination.

Sequence Rules Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons: The specification makes reference to specific polynucleotide and/or polypeptide sequences, see page 5 for example; these references must contain a sequence identifier of the form: SEQ ID NO: X. Appropriate correction is required.

Additionally, it is noted that the computer readable form of the sequence listing (CRF) received 1/6/2006 is good and has been entered into the database.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 48-55, 57, 61-66 and 75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 48-55, 57, 61-66 require that the antibody bind to 4-1BB on the T-cell clone "PL-1"; yet neither the art nor the specification sets forth the material elements that are definitive of a "PL-1" clone, thus the artisan could not be reasonably sure that he or she was in possession of the claimed invention.

Claim 75 requires a monoclonal antibody against 4-1BB. The phrase appears to be incomplete; it is unclear if the claim requires that the antibody be "raised against" 4-1BB or if some other parameter is required. The artisan could not reasonably gauge the metes and bounds of the claim as it is currently worded.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 52-55, 63-74 and 76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

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claimed invention. The claims require either agonist or antagonist antibodies however there is no description nor mention of such in the specification or claims as originally filed. This is a new matter rejection. On pages 9-11 of Applicants remarks of May 26, 2004 (and resubmitted November 15, 2006), Applicant asserts that support can be found for the claims at pages 4, 6, and 32, however, as stated above the specification appears to neither describe nor mention agonist or antagonist antibodies.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 48-51, 56-62 are rejected on the ground of nonstatutory double patenting over claims 2, 4, 6 of U. S. Patent No. 7138500 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

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The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: the instant claims and those in the patent are directed to monoclonal antibodies that bind human 4-1BB and the extracellular domain of human 4-1BB. The additional limitations of cell-type specific expression of 4-1BB are listed in the specification of the patent as being inherent features of the claimed antibodies, see pages 32-34. Additionally, the instantly claimed hybridomas are also essential features of producing monoclonal antibodies as disclosed in the patent and commonly understood in the art.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 52-55, 63-74, 76 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by claims 1-8 of U.S. Patent No: 6569997 to Kwon.

As set forth above claims 52-55, 63-74, 76 constitute new matter, are not supported by the instant specification, and are thus not afforded a priority date. Never the less, Kwon disclose and claim antagonistic and agonistic monoclonal antibodies, and hybridomas expressing same,

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that bind human 4-1BB (the instant SEQ ID NO: 8), wherein the antibodies are IgG isotypes and bind to T-cells (claims 1-8). Additionally, antibodies that recognize the extracellular domain of 4-1BB are encompassed by claims 1-8, see line 63, col 3, of prior application 08012269 which is now U.S. Patent No: 6362325. Furthermore, it would be expected that it is an inherent feature of the genus of antibodies claimed that they would bind 4-1BB under the various cell-type specific conditions as recited in the claims, absent evidence to the contrary.

Applicant is reminded that the Kwon reference is a U.S. patent that claims the rejected invention. An affidavit or declaration is inappropriate under 37 CFR 1.131(a) when the reference is claiming the same patentable invention, see MPEP § 2306. If the reference and this application are not commonly owned, the reference can only be overcome by establishing priority of invention through interference proceedings. See MPEP Chapter 2300 for information on initiating interference proceedings. If the reference and this application are commonly owned, the reference may be disqualified as prior art by an affidavit or declaration under 37 CFR 1.130. See MPEP § 718.

Claim 75 is rejected under 35 U.S.C. 102(e) as being anticipated by claim 2 of U.S. Patent No: 6974863 to Kwon.

Claim 75 is directed to antibodies binding any 4-1BB receptor protein. Claim 2 of U.S. Patent No: 6974863 claims an antibody produced from a hybridoma 53A2. The specification of the 6974863 patent teaches that this hybridoma produces monoclonal antibodies which specifically recognizes an epitope on the extracellular domain of receptor protein 4-1BB

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(murine), see line 65 col 3 to line 8 of col 4. This teaching is fully supported by prior application 08012269 which is now U.S. Patent No: 6362325, filed February 4, 1993, see line 63, col 3.

Applicant is reminded that the Kwon reference is a U.S. patent that claims the rejected invention. An affidavit or declaration is inappropriate under 37 CFR 1.131(a) when the reference is claiming the same patentable invention, see MPEP § 2306. If the reference and this application are not commonly owned, the reference can only be overcome by establishing priority of invention through interference proceedings. See MPEP Chapter 2300 for information on initiating interference proceedings. If the reference and this application are commonly owned, the reference may be disqualified as prior art by an affidavit or declaration under 37 CFR 1.130. See MPEP § 718.

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Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867. Official papers filed by fax should be directed to **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB



February 1, 2007


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SUPERVISORY PATENT EXAMINER
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